IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,	)	
	)	
Plaintiff and	)	
Counterclaim Defendant,	)	
	)	
v.	)	02: 02cv1628
	)	
MYLAN LABORATORIES, INC. and	)	
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendants and	)	
Counterclaim Plaintiffs.	)	

MEMORANDUM ORDER OF COURT

Presently before the Court is the MOTION IN LIMINE TO PRECLUDE PFIZER FROM PRESENTING EVIDENCE AND ELICITING TESTIMONY AT TRIAL REGARDING SECONDARY CONSIDERATIONS OF NONOBVIOUSNESS filed by Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively referred to as "Mylan"), to which Pfizer has filed a response in opposition and Mylan has replied. For the reasons discussed *infra,* the Motion will be denied.

Mylan seeks to preclude Pfizer "from presenting evidence and eliciting testimony at trial regarding 'secondary considerations' of nonobviousness." In response, Pfizer states that the "objective indicia of non-obviousness . . . are an important part of the analysis of obviousness and must always be considered in reaching a conclusion about obviousness." Pfizer's Resp. at 2.

As the United States Federal Circuit stated, "[e]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that

an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decision-maker remains in doubt after reviewing the art." *Strateflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983); *see also Iron Grip Barbell Co., Inc. v. USA Sports, Inc.,* 392 F.3d 1317, 1323 (Fed. Cir. 2004). Federal Circuit case law has identified, *inter alia,* commercial success and copying to be relevant factors in this inquiry. *See Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) (commercial success); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (copying).

Pfizer contends that it will offer evidence that is both relevant and probative of non-obviousness, evidence which will show commercial success, prior failures, and copying. It is well established that an invention's commercial success constitutes strong evidence of non-obviousness. *See., e.g., Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988). Federal Circuit case law clearly requires that a "nexus must be established between the merits of the claimed invention and evidence of commercial success before that evidence may become relevant to the issue of obviousness." *Iron Grip Barbell Co., Inc.*, 392 F.3d at 1324. However, the Federal Circuit has not found that the lack of such nexus evidence warrants preclusion. In such cases, courts simply accord little weight to the evidence; they do not preclude the admission altogether.

According to Mylan, "[w]hatever commercial success and professional approval Norvasc® has enjoyed is not due to the besylate salt of amlodipine that is the subject of the patent in suit, U.S. Patent No. 4,879,303 ("the '303 patent")." If this Court becomes convinced that there is no evidence of nexus, and that the evidence of commercial success was of no

significance at all, it would consider precluding the testimony in order to conserve time and resources. However, such a conclusion would be premature at this point. If, at trial, Pfizer fails to show that the commercial success of Norvasc® is due to the besylate salt of amlodipine that is the subject of the '303 patent, the Court will, as required by case law, accord the commercial success evidence little or no weight.

Like commercial success, a showing of prior failures and copying can be indicative of non-obviousness. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc*., 796 F.2d 443 (Fed. Cir. 1986) (failed attempts); *Akami Techs. Inc. v. Cable & Wireless Internet Servs., Inc.*, 68 U.S.P.Q.2d 1186 (Fed. Cir. 2003) (copying). As to prior failures, Pfizer intends to offer evidence to show that "[t]he Pfizer Pharmaceutical R&D department proceeded to work with amlodipine maleate for nearly two years without successfully making a commercial tablet formulation because of stability and processing problems. Only then it recommended either changing to a different salt of amlodipine or abandoning amlodipine itself in favor of a different therapeutic compound." Pfizer Resp. at 2.

Additionally, Pfizer intends to offer evidence to show that Mylan has "copied the amlodipine besylate salt because its experience with amlodipine maleate and its testing of the other salts demonstrated the superiority of the invention." Pfizer Resp. at 5. As the Federal Circuit held in *Speciality Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1998), "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."

After hearing all the evidence admitted during the trial, the Court will determine how much weight, if any, to accord to Pfizer's evidence of prior failures and copying.

For the aforementioned reasons, the Motion to Preclude Evidence of Secondary Considerations filed by Mylan will be denied.

So **ORDERED** this 17th day of November, 2006.

BY THE COURT:

s/Terrence F. McVerry
United States District Court Judge

cc: All Counsel of Record